TRICARE Northwest Regional Prescribing Guideline for use of Proton Pump Inhibitor (PPI) in treatment of GERD

The purpose of this prescribing guideline is to provide information pertaining to the use of medications for the treatment of Gastroesophageal Reflux Disease (GERD) in **adult patients**. Not all patients may respond to the therapy outlined in this guideline. For those situations, providers should consult the medical literature for more extensive information on the management of GERD.

Uninvestigated dyspepsia is NOT an indication for PPI use unless part of *H. Pylori* treatment.
Ranitidine should be used instead.

Initiation of PPI

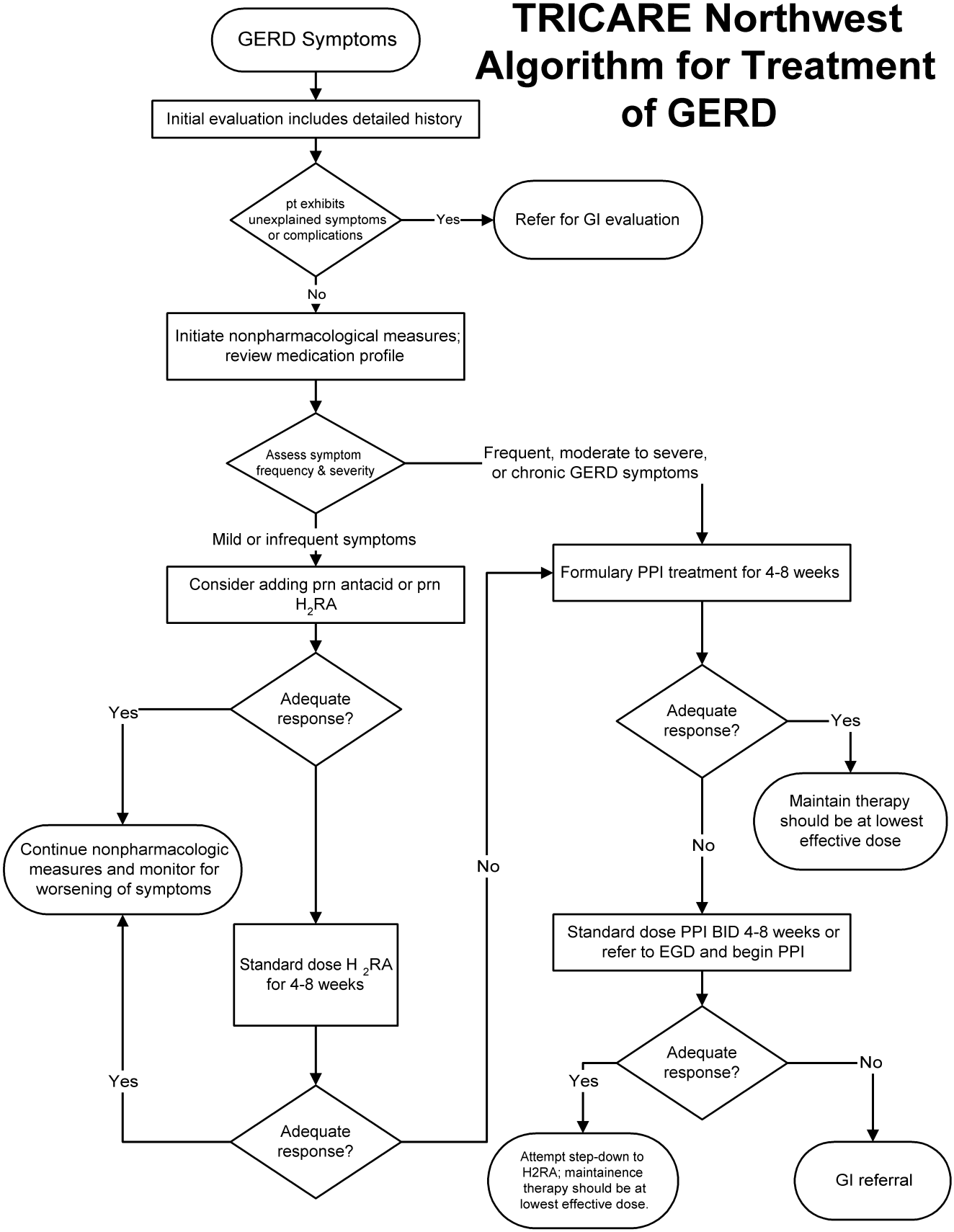
See algorithm for treatment of GERD next page

Dosing

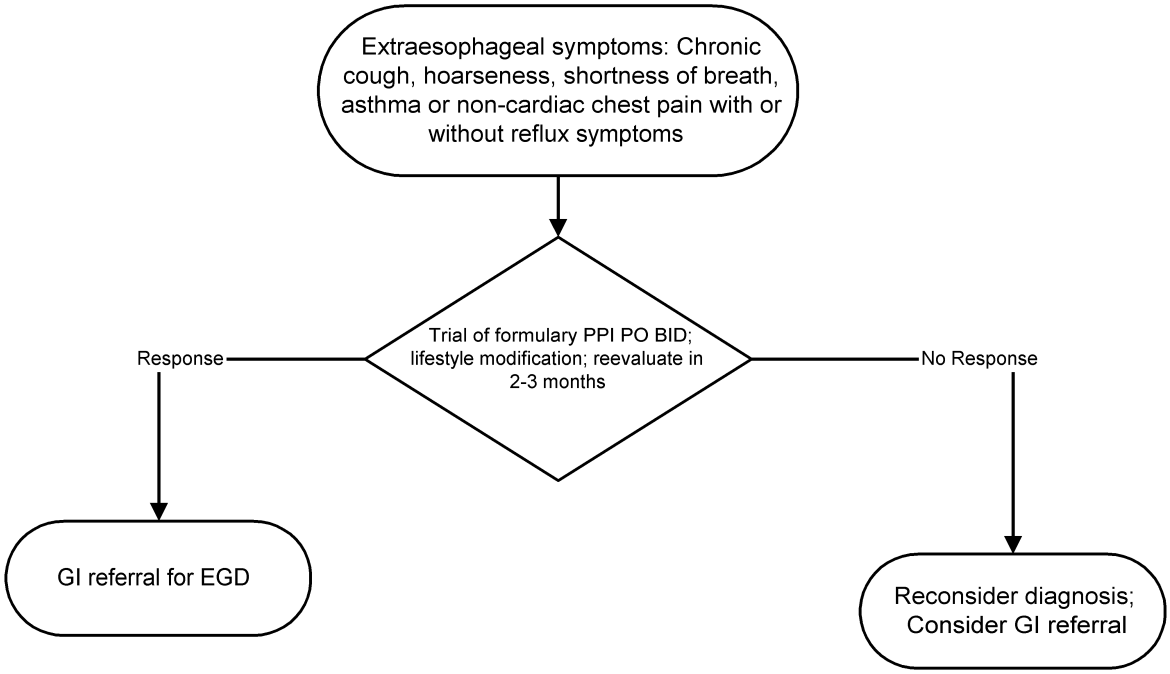
- **Prescriptions written for lansoprazole 15mg BID (or 30mg QD) or omeprazole 10mg BID (or 20mg QD) will be automatically converted to raberprazole 20mg QD unless justification is appropriately documented.**
- **For patients with difficulty swallowing, lansoprazole capsule may be opened and sprinkled on applesauce or mixed with juice for administration in patients with NG tube.**
- **Pharmacotherapeutic agents for GERD management**

Class	Antacid	H_2RA	PPI
Place in therapy	Initial therapy: Mild or infrequent reflux symptoms	Standard dose: Inadequate response to diet/lifestyle modification. Antacids, or nonprescription H_2Ras High dose: Inadequate response to standard dose therapy, or as initial treatment for moderate to severe symptoms	Complicated GERD: Ulcerative esophagitis, stricture, Barrett's esophagus, atypical symptoms; refractory to high dose H_2RAs

TRICARE Northwest Algorithm for Treatment of GERD



TRICARE Northwest Algorithm for Treatment of GERD Extraesophageal Symptoms



Diagnostic Definitions

Gastroesophageal Reflux Disease (GERD): Defined by a typical history of heartburn (pyrosis), regurgitation, or both, which often occurs after meals (especially large or fatty meals). Heartburn is often described as a rising epigastric or retrosternal burning sensation. Regurgitation is described as sour taste or gastric contents in the mouth. these symptoms are often aggravated by recumbency or bending and are relieved by antacids.

Dyspepsia: Episodic or persistent abdominal symptoms, often related to meals, which patients or physicians believe to be due to disorders of the proximal digestive tract. This usually manifests as an epigastric discomfort, accompanied by fullness, burning, belching, nausea, vomiting, fatty food intolerance or difficulty completing a meal; bowel habits usually remain unaltered (see Referral Guidelines for Dyspepsia).

Lifestyle Modification for Patients with GERD : Decrease or eliminate intake of fatty or spicy foods, grapefruit or orange juice, chocolate, peppermint, coffee, tea, colas, and alcohol. Eat smaller meals. Stay upright 2-3 hours after meals. Stop smoking. Avoid tight clothing over the abdomen. If overweight, lose weight and achieve ideal body weight. If symptoms are particularly bothersome at night, raise the head of the bed 2-6 inches with wood blocks or bricks.

Patient-directed Therapy: Antacids and over-the-counter histamine type-2 antagonists (H_2RAs) are equally effective in treating symptoms. Antacids should be taken 30 minutes after eating and provide a more rapid response. H2RAs should be taken 30 minutes before eating and have a much longer duration of action.

a. GERD-Gastroesophageal reflux disease; GI-gastrointestinal; H_2RA-histamine 2 receptor antagonist; PPI-proton pump inhibitor: EGD-esophagogastroduodenoscopy

b. Patients with complications of advanced disease should be referred immediately to a GI specialist. Some experts also recommend referral to rule-out Barrett's esophagus in patients with a long history of symptoms. However, it is unclear if early diagnosis influences outcome.

Classification	Patient presentation
Typical symptoms	Heartburn, regurgitaion, waterbrash
Extraesophageal manifestations	Chronic cough, noncardiac chest pain, hoarseness, globus sentation, respiratory symptoms, dental disease
Complications of advanced disease	Difficulty swallowing (dysphagia), painful swallowing (odynophagia), esophageal stricture, Barrett's metaplasia, perforation, hemorrhage, anemia, weight loss

c. Non-pharmacologic measures to reduce GERD symptoms

dietary	Decrease fat intake, reduce/eliminate intake of foods or beverages which exacerbate symptoms (i.e. alcohol, caffeine, peppermint/spearmint, chocolate, citurs, milk, onions, garlic, spicy foods, tomato juice), consume meals of smaller volume, avoid recumbent position for 3 hours after a meal.
lifestyle	Elevate head of bed 6-8 inches, avoid tight clothing, weight reduction if appropriate, smoking cessation,

d. Some medications may decrease lower esophageal sphinter pressure or cause direct injury to the esophageal mucosa.

e. Symptoms do not always correlate with disease severity; symptoms assessment should take into consideration impact on quality of life. Referral to a GI specialist may occur at any time depending on patient symptoms and clinician preference; some practitioners embrace the approach of early referral for once in a lifetime EGD in all patients requiring chronic pharmacologic therapy.

f. Recommended Dosages of Medications used in GERD/Reflux Esophagitis

Drug	Recommended dosing(oral)	Dose adjustment in renal/hepatic impairment	Comments
antacids	15-30ml QID, PC and HS		Use for 2-4 weeks then as needed. Sucralfate has also been used for treatment of mild to moderate GERD.
cimetidine	Standard dose 400mg BID or 800mg HS High dose 400mg QID or 800mg BID	CrCl>30ml/min, 800mg HS CrCl 15-30ml/min, 600mg HS CrCl<15ml/min, 300-400mg HS	More frequent dosing results in greater symptomatic improvement and healing in patients with more severe disease. Recommended duration of therapy is 8 to 12 wks.
ranitidine	Standard dose 150mg BID or 300mg HS High dose 150mg QID or 300mg BID	Crcl<50ml/min, 150mg HS	
Raberprazole	Standard dose 20mg QD x 8 weeks Maintenance 20mg QD	Dosage adjustment should be considered in patients with severe hepatic disease	

g. Consider prn H_2RA or antacids for symptom control. Reinstate therapy if patient relapses; consider maintenance for frequent relapses.
h. Consider step-down therapy if appropriate; reinstitute therapy if patient relapses.

Response	Step-down Therapy	Chronic Therapy
Symptoms Resolve: complete course of therapy; then discontinue agent or maintain at lowest dose to control symptoms. Relapse in symptoms: Treat with another course of therapy (similar to or more potent than initial therapy); if on maintenace, dose should be reassessed or agent changed.	Response to standard dose H_2RA: Trial prn H_2RA or antacid. Response to high dose H_2RA: Trial standard dose H_2RA for maintenance. Response to PPI: Attempt trial on H_2RA, with maintenance at lowest effective dose. Not responding to step-down: Maintenance therapy with agent that originally provided symptom control. Higher grade esophagitis: Relapse more likely to occur, step-down may not be appropriate. Control symptoms with least number of medications, at lowest possible dose; some may respond to repeated short course of treatment.	Due to the chronicity of GERD, high % patients will require long-erm therapy to control symptoms or prevent recurrence of esophagitis. Patients on long-term (≥5 years) antisecretory therapy for symptom control may be referred for EGD to determine presence of Barrette's esophagus or malignancy.

i. Evidence not conclusive to recommend preferred strategy. EGD will rule-out Barrett's esophagus or malignancy, assess degree of mucosal injury, and in patients with esophagitis, identify those likely to need maintenance PPI. Choice of therapy should take into account age and lifespan, availability and risk of EGD, patient preference, and additional clinic visits to step-down therapy.

Drug cost per month as of 02/2002

Lansoprazole 15mg BID	$ 58.72§	($0.98/15mg single dose)
Lansoprazole 30mg QD	29.36§	(0.98/30mg single dose)
Omeprazole 10mg BID	19.19§	(0.32/10mg single dose)
Omeprazole 20mg QD	61.65§	(2.05/20mg single dose)
Rabeprazole 20mg QD	6.56§	(0.22/20mg single dose)
* Ranitidine 300mg BID	3.70	(0.06/150mg single dose)

* Denotes DoD/VA National Contract
§ Prices may vary based on container size